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ALERT

Reforming GRAS: Digesting the Proposed "Better Food Disclosure Act" (S. 3122)

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Senator Roger Marshall (R-KS) introduced much-anticipated legislation this month that seeks to reform the process by which "generally recognized as safe" (GRAS) substances are assessed by the U.S. Food and Drug Administration (FDA). Specifically, this legislation would require mandatory notification for all GRAS substances and end the "self-affirmed" GRAS pathway as a means of bringing new food ingredients to market for both human and animal foods.

The Better Food Disclosure Act of 2025, also known as the Better FDA Act (S. 3122), proposes amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) that would (1) mandate notification of all GRAS substances to the FDA (including those currently on the market), (2) require FDA to create a public listing of GRAS substances, and (3) establish a post-market review process to assess the continued safety of food additives, color additives, and GRAS substances.

Notably, the bill does not contain a preemption provision that would address the recent patchwork of state laws prohibiting or restricting the use of certain food ingredients and color additives in food products in the state. It has been reported that this was removed after Senator Marshall received significant pushback from members of the Make America Healthy Again (MAHA) movement.

Current Regulatory Framework

Under the FDCA, new food additives must be approved by the FDA before the additives may be used in food. However, food substances that are concluded to be GRAS by a company can be marketed without prior FDA review or approval. FDA regulations provide

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rigorous criteria for concluding a substance is GRAS, including establishing that there is "common knowledge throughout the relevant scientific community ... that there is reasonable certainty that the substance is not harmful under the conditions of its intended use." The two pathways established by the FDCA and the FDA GRAS Rule allow GRAS substances to be marketed through:

1. *Self-conclusion* in which a company self-concludes a substance is GRAS without prior notification to the FDA by confirming the substance meets the condition of the GRAS Rule. Such substances are often referred to as "self-affirmed GRAS substances."
2. *Voluntary* notification to the FDA in which a company can submit its GRAS conclusions. If FDA does not question the basis for the submitter's GRAS conclusion, it will issue a "no questions" letter to the submitter indicating it will not object to distribution in the U.S consistent with the GRAS notice. Such substances are frequently referred to as "GRAS notified."

Key Provisions of the Better Food Disclosure Act of 2025

Mandatory GRAS Notification and Listing

Under the proposed legislation, a food substance generally recognized as safe would be deemed "adulterated" under Section 402(a)(2)(C) of the FDCA unless the substance is: (1) "listed" by the FDA in the required GRAS listing database, or (2) is under FDA review for a GRAS listing. The bill requires FDA to establish and maintain a publicly accessible list of all GRAS substances (the GRAS List).

The bill provides that manufacturers intending to use a food substance generally recognized as safe may file with the FDA a notice proposing that such food substance be included on the GRAS List. Manufacturers of existing GRAS substances will have two years after the bill is enacted to file the required notification with FDA for their GRAS substances. Manufacturers of new GRAS substances introduced for use in food after enactment of the bill must notify FDA at least 120 days before the first use of the substance. The bill does not state what information will be required to be included in the mandatory notifications.

Once a notice is received by the FDA, the bill requires FDA to "accept such notice" and respond within 180 days by either (1) listing the substance in the GRAS List, or (2) issuing a preliminary exclusion. If the FDA does not respond to the notice within the required 180-day time frame, the substance will be automatically "deemed to be added to the list."

If the FDA decides to exclude or remove a substance from the GRAS List, the user of the substance must submit one of the following within 180 days: (1) a request for reconsideration, (2) a food additive petition, or (3) a plan to phase out the substance. If a request for reconsideration is submitted under this provision, the FDA must make a final determination with respect to the substance within 180 days of receiving "sufficient information" to make its determination.

Post-Market Assessment Provision

The proposed legislation also includes a provision that allows FDA to reevaluate GRAS substances, food additives, or color additives based on citizen petitions, notices from state officials, or its own initiative. The bill requires FDA to prioritize such reviews based on "clear and convincing scientific evidence" supporting the petition. If FDA decides a review is warranted, FDA will publish a notice in the Federal Register requesting data to support the reevaluation of the substance under review. Based on its review, FDA could amend or revoke food additive regulations, reclassify GRAS substances as food additives, or remove substances from the GRAS List.

Definitions

The proposed legislation revises the definition of "food additive" under FDCA Section 201(s) (21 U.S.C. 321(s)) to remove the existing GRAS clause from the definition and provides an affirmative new definition for "a food generally recognized as safe" in a new FDCA Section 201(tt) as:

"any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, except that such term does not include [food additives, pesticide chemical residues, pesticide chemicals, color additives, prior sanctioned ingredients, new animal drugs, or dietary ingredients]."

The proposed definition for "a food substance generally recognized as safe" largely tracks the language in the current food additive definition, subjecting the GRAS substances to the same conditions and exclusions that currently apply to such substances under the FDCA.

Lack of Funding

Notably, the bill does not provide any additional FDA funding to support this new regulatory review process, which would clearly make meaningful implementation of this bill a significant challenge. Without funding, presumably many of the timelines in the bill would pass before FDA could meaningfully review submissions.

The Bill Lacks Important Details

The proposed legislation lacks detail on several important issues necessary for food companies to understand their responsibilities if enacted. Several examples include:

- Under the bill's review timeline requirements, once 180 days have passed after submission of a notice to the FDA, the food substance would be deemed to be added to the new GRAS List. However, the bill does not state how anyone other than the entity that submitted the substance would know that the

substance had been *deemed* to be added to the GRAS List. This could cause confusion regarding the legal status of the substance.

- The bill would require companies currently marketing a GRAS substance to file notices to propose inclusion on the GRAS List within two years of enactment. However, because the bill provides no detail on what information should be included in the notice, we do not yet know what information FDA would require in those notices to make them sufficient for FDA's review. Another greater potential complication is that the bill would not require FDA to finalize a regulation with FDA requirements until two years *after enactment*, leaving no direction for food manufacturers during the same period of time when many notices would need to be filed.
- The bill does not specifically address the status of GRAS substances already subject to an FDA GRAS affirmation regulation or to an FDA "no questions" letter prior to enactment. It is unclear whether such food substances will automatically be added to the new GRAS List or whether a notification will need to be submitted for inclusion on the new GRAS List.

What Does This Mean for Clients

1. **The introduction of this bill constitutes another step taken in support of the MAHA movement.** MAHA priorities continue to remain a focal point of this Administration's agenda. It is clear that MAHA has gained significant momentum and influence under the current Administration, and clients should be aware of and monitor MAHA's policy objectives at both the state and federal level to anticipate future changes for food policy.
2. **FDA is still expected to release a proposed rule modifying the GRAS pathway later this year.** The Spring Unified Agenda (RIN: 0910-AJ02) stated that FDA intends to release its proposed rule requiring mandatory submission of GRAS ingredients in October 2025. While it is likely the government shutdown delayed release of the proposed rule, this proposed rule may be released at any time. By planning to impose mandatory GRAS notification through regulation, not only is FDA not waiting for Congress to make a change to the GRAS process, but it is also asserting it has statutory authority to require mandatory notification without congressional amendments to the law. This assertion is inconsistent with FDA's historical position that it lacks express authority to require notification of GRAS substances prior to marketing. Food companies should be monitoring for the publication of this proposed rule and be prepared to submit comments.
3. **State legislatures continue to introduce and pass legislation banning and restricting food ingredients for use in the state.** During the 2025 session, at least 108 bills across 17 states have been introduced in state legislatures related to food ingredients, SNAP, nutrition education, ultra-processed foods, and physical activity in schools. Unless a federal standard is enacted, food companies should continue to monitor the patchwork of state laws introduced to understand their regulatory compliance obligations.

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Wiley will continue monitoring the progress of this bill and providing any updates regarding GRAS legislation and rulemaking. For more information on how the proposed Better Food Disclosure Act could affect your business, please reach out to our team of interdisciplinary attorneys.

Emma Howard, a Law Clerk at Wiley Rein LLP, contributed to this alert.